EXHIBIT E

Crystal Kettenbeil

From: Eric Stubenvoll
Sent: Friday, August 22, 2008 1:41 PM
To: Crystal Kettenbeil
Subject: FW: Cahill- Supplemental Discovery Responses
Attachments: Cahill- Suppl Ans to Pltf_s Rogs.PDF; Cahill- Suppl Ans to Pltf_s RFP.PDF; Cahill Suppl Doc Prod-MedWatch Reports.PDF; Cahill-COS for suppl discovery.PDF

From: Nicole Young-Kuykendall [mailto:nkuykendall@smbtrials.com]
Sent: Friday, August 15, 2008 3:12 PM
To: Eric Stubenvoll
Cc: Kay Schichtel; Anthony Monaco
Subject: Cahill- Supplemental Discovery Responses

Eric,

Please find attached Smith & Nephew's Supplemental Answers to Plaintiff's Discovery and responsive documents. A copy will be sent via US Mail as well.

Yours truly,
Nicole

Nicole M. Young-Kuykendall, Esq.
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY THERESA CAHILL, Plaintiff,	)	
vs.	)	No. 08 C 255
SMITH & NEPHEW, INC.,	)	District Judge Darrah
Defendants.	)	Magistrate Brown

PROOF OF SERVICE

I, Nicole M. Young-Kuykendall, an attorney, hereby certify that on August 15, 2008, I served Smith & Nephew, Inc.'s Supplemental Answers to Plaintiff's First Set of Interrogatories and Supplemental Responses to Plaintiff's First Request For production via e-mail and regular U.S. Mail to the following:

Eric D. Stubenvoll
Fisher Kanaris, P.C.
200 South Wacker Drive, 22nd Floor
Chicago, Illinois 60606
(312) 474-1413/(312) 474-1410 FAX
ATTORNEY FOR PLAINTIFF

Respectfully submitted,

Nicole M. Young-Kuykendall

Kay L. Schichtel ARDC #2480417
Anthony J. Monaco, ARDC #6279545
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330 N. Wabash, Ste. 3300
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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY THERESA CAHILL, Plaintiff,	)	
vs.	)	No. 08 C 255
SMITH & NEPHEW, INC.,	)	District Judge Darrah
Defendants.	)	Magistrate Brown

SMITH & NEPHEW, INC.'S SUPPLEMENTAL ANSWERS TO PLAINTIFF'S FIRST SET OF INTERROGATORIES

Smith & Nephew, Inc. supplements its answers Plaintiff's first set of interrogatories as follows:

INTERROGATORIES

1. Identify each person who assisted in preparing the answers to these interrogatories and, following the identity of each such person, state the number of each interrogatory for which that person provided assistance.

ANSWER: Objection on the grounds that the interrogatory is overbroad and unduly burdensome. Without waiving this objection and by way of response, Smith & Nephew, Inc. states that it is a corporate defendant. As such, these responses were not "answered" by any one person. These responses were prepared by Smith & Nephew, Inc. with the assistance of retained counsel. Dennis Watson, Assistant Secretary, has signed these responses on behalf of Smith & Nephew, Inc.

2. State whether or not this defendant is being sued in its full and correct name. If not, state the full and correct name of this defendant.

ANSWER: Defendant is being sued in its full and correct name.

3. Do you have any statements from any witnesses? If so, give the name, present or

last known address, telephone number, job title, employer, of each such witness, the date of the statement and whether the statement was written or oral.

ANSWER: None other than those produced and supplied by plaintiff or subpoenaed with notice to all parties.

4. State whether there exists photographs of the hip prosthetic referenced in the Complaint. If so, state the following:

(a) Describe each photograph;
(b) State the date each was taken;
(c) State the name and address of the person taking each such photo

ANSWER: See enclosed 11 photographs.

5. State whether or not any insurance company (including any company with excess or umbrella coverage) has an interest in the outcome of this litigation against defendant. If so, state the following:

(a) The name of the insurance company;
(b) Whether the insurance company is a stock company or a mutual company;
(c) Name of the insured;
(d) Type(s) of insurance;
(e) Effective policy period;
(f) Policy number; and
(g) Limits of the policy applicable to the occurrence mentioned in these pleadings.

ANSWER: Smith & Nephew, Inc. is self-insured in an amount sufficient to cover any potential liability in this matter.

6. Please state whether you were the manufacturer of the hip prosthetic referenced in plaintiffs Complaint, and if so, please state:

(a) The date upon which the subject product was manufactured;
(b) The address of the factory and/or such other place at which the subject product was manufactured;
(c) Whether, at the time of the manufacturer of the subject product, you had a quality control department and/or individual, or a department

and/or individual denominated by a different name which was primarily responsible for quality control procedures for the subject product; and

(d) If your answer to the foregoing subpart was in the affirmative, the identity of the supervisor and/or person primarily responsible for implementing the quality control procedures, if any, with respect to the subject product.

ANSWER: Smith & Nephew, Inc. manufactured the hip prosthetic referenced in plaintiffs Complaint.

(a) April 2002.
(b) Objection. Relevance. Notwithstanding this objection, Tennessee.
(c) Objection. Whether Smith & Nephew currently maintains a quality control department or division is of no relevance to any issue in this case. Moreover, the request is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. Notwithstanding this objection, see Manufacturing Records.
(d) See (c) above.

7. Please identify any and all production specifications formulated and/or utilized by you in the manufacturing of the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: See Manufacturing Records, 510K, and Print.

8. Please identify each person who had a responsibility to oversee or supervise the manufacturing of the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: Objection. "Each person who had a responsibility to oversee or supervise the manufacturing of the hip prosthetic referenced in plaintiff's Complaint" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant.

9. Please state whether you designed the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: Smith & Nephew, Inc. designed the hip prosthetic referenced in plaintiff's Complaint.

10. If your answer to the foregoing interrogatory is affirmative, please identify:

(a) The date or dates upon which the subject product was designed;
(b) The location of the facility where the subject product was designed;
(c) The name(s) of the person(s) who participated in the design;
(d) An identification of each and every drawing, plan, or document relating to the design of the subject product;
(e) Whether any such document, plan or drawing identified in your answer to subparagraph (d) has been submitted to any governmental entity for approval, registration, or patent, and if so, the date of said submission and entity to which such document was submitted.

ANSWER:

(a) See Print.
(b) See Print.
(c) Objection. "Name(s) of the person(s) who participated in the design" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant;
(d) See Print;
(e) See 510K.

11. Do you contend that the retailer who supplied the hip prosthetic referenced in plaintiff's Complaint was aware of any alleged defect in such product?

ANSWER: The subject product was not supplied by a retailer.

12. If your answer to the foregoing interrogatory is in the affirmative, please identify:

(a) Each and every fact upon which you base such contention;
(b) The name, business and residence address, and telephone number of any person having knowledge of any such facts; and
(c) An identification of each and every writing relating to any such fact.

ANSWER: See answer to No. 11 above.

13. Please state whether you provided any written instructions or warnings as to the use or installation of the hip prosthetic referenced in plaintiff's Complaint.

ANSWER: Objection. The terms "use or installation" are vague and improper when

used in the context of this lawsuit. Notwithstanding this objection, Smith & Nephew, Inc. included the Package Insert when it sold the hip prosthetic referenced in plaintiff's Complaint.

14. If your answer to the foregoing interrogatory is in the affirmative, please identify:

(a) The written instructions or warnings;
(b) The name, business and residence address, and telephone number of the person(s) who drafted the wording of said instruction; and
(c) Each and every writing relating to the composition of all printed matter distributed with or affixed to the product.

ANSWER:

(a) See Package Insert;
(b) Objection. "The name, business and residence address, and telephone number of the person(s) who drafted the wording of said instruction" is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. David Kelman, Group Director of Hip Development, is a person who is familiar with the subject implant; and the information in the Package Insert.
(c) Objection. This request is an extremely overbroad and unduly burdensome request that is nothing more than a fishing expedition. See Package Insert.

15. Identify any and all complaints, lawsuits, or claims submitted to you relating to the alleged defect(s) of similar makes and models of the hip prosthetic referenced in plaintiffs Complaint.

ANSWER: Objection. This request is not limited to the product involved in this case, not limited to the nature of the allegations in this case, not limited in time or in scope and is extremely overbroad and not reasonably calculated to lead to the discovery of admissible evidence. In addition, the request seeks information protected by the attorney-client privilege and work-product doctrines. Notwithstanding these objections, Smith & Nephew states that it has searched its records for the period of January 1, 2001 through May 2, 2008 and states that it has received no other lawsuits and one other claim alleging a fracture of Echelon Hip Model No. 7130413. The claim involved a patient in Ontario Canada. **Notwithstanding these objections, Smith & Nephew provides the attached documents.**

16. Please state whether you performed any test, of whatever nature or description, for the purpose of determining whether the hip prosthetic referenced in plaintiffs Complaint met

reasonable performance expectations for its intended use.

ANSWER: Objection. The term "test" is vague and undefined. In the context of litigation "test" can mean a number of things. Notwithstanding these objections, see Manufacturing Records.

17. If your answer to the foregoing interrogatory is affirmative, please identify:

(a) A description of each such test conducted by you;
(b) The date and location where each test was conducted;
(c) Whether any aspect of any such test was recorded or memorialized or any document or writing, including photographs, films, videotapes or other visual representations of whatever nature or description;
(d) An identification of any such document or visual representation;
(e) Whether the results of any such test(s) were submitted, or referred to in any manner whatsoever, and any document filed with or tendered to any public entity or regulatory agency; and,
(f) The name, business and residence address, and telephone number of the person(s) charged with the responsibility to evaluate the performance of the subject product in each such test referred to in your answers to the proceeding subparts of this interrogatory.

ANSWER: See No. 16 above.

18. Identify any facts known to you indicating that the hip prosthetic referenced in plaintiffs Complaint had been altered or modified between the time it left the manufacturer's custody and the time it was implanted.

ANSWER: None known at this time. Discovery is on-going. Investigation continues.

19. Identify any facts or circumstances known to you indicating that plaintiff was not using the hip prosthetic referenced in plaintiffs Complaint in a manner reasonably anticipated.

ANSWER: Unknown at this time. Discovery is on-going. Investigation continues.

20. State the name of each expert witness that you expect to testify at the trial of your

claims in this case, and for each such witness provide the following:

(a) The subject matter on which the witness will testify;
(b) The conclusions and opinions of the witness, and the bases therefore;
(c) The qualifications of the witness;
(d) Any report prepared by the witness about the case;
(e) Any exhibits to be used as a summary of or support for the opinions;
(f) The compensation to be paid in relation to the witness's testimony and preparation therefore; and
(g) A list of any other cases in which the witness has testified as an expert at trial or by deposition within the last four years.

ANSWER: Unknown at this time. Defendant will disclose its experts in accordance with the court's scheduling order.

21. State the names and addresses of all fact witnesses you expect to call at the trial of your claims in this case and state what you expect to be the substance of each witness' testimony.

ANSWER: Unknown at this time. Defendant's first notice of this claim was upon service of the complaint. Defendant expects that any witnesses to the incident may be called to testify. The identity of those witnesses is in the exclusive control of the plaintiff. In addition, defendant anticipates that plaintiff's treating physicians (pre and post incident) may have relevant information. See plaintiff's deposition. At this time, defendant is unsure which fact witnesses have relevant information. Once plaintiff produces his final Rule 26 expert report and defendant is apprised of the specific defect claimed, defendant will be in a position to identify all fact witnesses that have relevant information and who may be called to testify at trial. Therefore, defendant expects to supplement this response in the future.

Respectfully submitted,

SMITH & NEPHEW, INC.

By: _____
One of its attorneys

Kay L. Schichtel
Anthony M. Monaco, ARDC 6279545
Nicole M. Young-Kuykendall, ARDC 6294692
Swanson, Martin & Bell, LLP
330 N. Wabash St., Suite 3300
Chicago, IL 60611

(312) 321-9100
(312) 321-0990 FAX

VERIFICATION

Under penalties as provided by law, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that he verily believes the same to be true.

Dennis Watson
Assistant Secretary
Smith & Nephew, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY THERESA CAHILL, Plaintiff,	)	
vs.	)	No. 08 C 255
SMITH & NEPHEW, INC.,	)	District Judge Darrah
Defendants.	)	Magistrate Brown

SMITH & NEPHEW INC.'S SUPPLEMENTAL RESPONSES TO PLAINTIFF'S FIRST REQUEST FOR PRODUCTION

Smith & Nephew, Inc.'s responds to plaintiff's first request for production as follows:

1. All documents that evidence, related to, or in any way substantiate your answers to the plaintiff's Interrogatories.

RESPONSE: All documents are identified and produced in response to specific requests.

2. All non-privileged statements or other writings summarizing or containing statements of any party relating to the incident alleged in the plaintiff's Complaint and/or the injuries and damages allegedly resulting therefrom.

RESPONSE: None other than medical records which were subpoenaed with notice to all parties.

3. All photographs, slides, motion pictures, models, videotapes, and/or exhibits of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: See 11 photographs enclosed.

4. All documents related to the manufacturing of the hip prosthetic referenced in plaintiff's Complaint, including but not limited to drawings and specifications.

RESPONSE: Objection. The term "documents" is undefined and overbroad. Notwithstanding this objection, see Manufacturing Records, Print and 510K.

5. All instructions related to the to the hip prosthetic referenced in plaintiff's complaint.

RESPONSE: Objection. The term "instructions" is undefined and overbroad. Notwithstanding this objection, see Package Insert and Surgical Technique.

6. Any applicable safety standards or codes considered, governing, or used in the design and/or manufacture of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. This request is overbroad because it is not limited in scope and to the issues in this lawsuit. Notwithstanding these objections, see attached Manufacturing Records, Print, and 510K.

7. All warnings related to the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. The term "warnings" is undefined and overbroad. Notwithstanding this objection, see plaintiff's medical records, the Package Insert, and the Surgical Technique.

8. Any report prepared by any expert witness about the case, including any exhibits to be used as a summary of or support for the opinions.

RESPONSE: None at this time. Smith & Nephew will supplement this in accordance with the court's scheduling order.

9. Any and all documents relating to testing performed by or for defendant related to the hip prosthetic referenced in plaintiff's Complaint including results of any testing or inspection for safety of the product.

RESPONSE: Objection. The term "testing" is undefined and can mean a wide variety of things in litigation and thus, the interrogatory is vague and ambiguous. Notwithstanding this objection, see the Manufacturing Records.

10. All documents reflecting the origin, manufacturer, date of manufacture, and purchaser of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. The term "origin" is vague and ambiguous. Notwithstanding these objections, see Manufacturing Records.

11. Copies of any and all documents relating to any claim, complaint, report or incident similar to plaintiff's claim as referenced in the Complaint.

RESPONSE: Objection. This request is not limited to the product involved in this case, not limited to the nature of the allegations in this case, not limited in time or in scope and is extremely overbroad and not reasonably calculated to lead to the discovery of admissible evidence.

In addition, the request seeks information protected by the attorney-client privilege and work-product doctrines. Notwithstanding these objections, Smith & Nephew states that it has searched its records for the period of January 1, 2001 through May 2, 2008 and states that it has received no other lawsuits and one other claim alleging a fracture of Echelon Hip Model No. 7130413. The claim involved a patient in Ontario Canada. **Notwithstanding these objections, Smith & Nephew provides the attached documents.**

12. Any and all brochures, manuals, parts lists, instructions, written materials, advertising materials, or other documents relating to the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. This request is overbroad and not limited in time, scope or to the issues raised in this lawsuit. Notwithstanding these objections, see the 6 marketing brochures.

13. Copies of warranties given to the purchaser(s) of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: None.

14. Any and all documents, records, or tangible evidence that the product was altered or modified between the time it was sold and the date of the Occurrence in question.

RESPONSE: Unknown at this time. Discovery is on-going. Investigation continues.

15. Any and all documents or records evidencing that this defendant complied with all applicable statutes, regulations, and standards existing at the time of manufacture that prescribed standards for design, inspection, testing, manufacture, labeling, packaging, or instruction for use of the hip prosthetic referenced in plaintiff's Complaint.

RESPONSE: Objection. The terms "documents" and "records" are undefined and overbroad. In addition, this request is not limited to the issues raised in this lawsuit. Notwithstanding these objections, see 510K and Manufacturing Records.

Respectfully submitted,

SMITH & NEPHEW, INC.

By: _____
One of its attorneys

Kay L. Schichtel
Anthony M. Monaco, ARDC 6279545
Nicole M. Young-Kuykendall, ARDC 6294692
Swanson, Martin & Bell, LLP
330 N. Wabash St., Suite 3300
Chicago, IL 60611

(312) 321-9100
(312) 321-0990 FAX

VERIFICATION

Under penalties as provided by law, the undersigned certifies that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that he verily believes the same to be true.

Dennis Watson
Assistant Secretary
Smith & Nephew, Inc.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
3500A Facsimile

Smith & Nephew, Inc., Orthopaedic Division

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Reisys International Inc., FDA Facsimile Approval: 4/17/2007

Mfr Report #

User/Importer Report # 1020279-2008-00179

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: P.L. In confidence
2. Age at Time of Event: or Date of Birth: 77 / 11/20/1930
3. Sex: [X] Female [ ] Male
4. Weight: UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death (mm/dd/yyyy)
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [X] Required intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/22/2008
4. Date of This Report (mm/dd/yyyy): 06/02/2008

5. Describe Event or Problem

It was reported that revision surgery was performed after the patient fell resulting in femur fracture and prosthesis fracture.

6. Relevant Tests/Laboratory Data, Including Dates

UNK

7. Other Relevant History, including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
1.
2.

2. Dose, Frequency & Route Used
1.
2.

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
1.
2.

4. Diagnosis for Use (Indication)
1.
2.

5. Event Abated After Use Stopped or Dose Reduced?
1. [ ] Yes [ ] No [ ] Doesn't Apply
2. [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
1.
2.

7. Exp. date
1.
2.

8. Event Reappeared After Reintroduction?
1. [ ] Yes [ ] No [ ] Doesn't Apply
2. [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Echelon
2. Common Device Name: Stem
3. Manufacturer Name, City and State: Smith & Nephew Inc., Orthopaedic Div. 1450 Brooks Road Memphis, TN 38116 USA

4. Model #: UNK
Lot #: UNK
Catalog #: 71340812
Expiration Date (mm/dd/yyyy): UNK
Serial #: NA
Other #: NA

5. Operator of Device: [X] Health Professional [ ] Lay User/Patient [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy): 05/22/2007
7. If Explanted, Give Date (mm/dd/yyyy): 05/05/2008

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [X] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [X] Returned to Manufacturer on 06/02/2008 (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
UNK

E. INITIAL REPORTER

1. Name and Address
Phone # 07176577342
Craig Holman,
PINNACLE HEALTH SYSTEM
PO BOX 8700
HARRISBURG, PA 17105,

2. Health Professional? [ ] Yes [X] No
3. Occupation: Sales rep
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [X] Unk.

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH
3500A Facsimile (Back) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/ Importer Report Number:
3. User Facility or Importer Name/Address:

4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):
7. Type of Report: ☐ Initial ☐ Follow-up #
8. Date of This Report (mm/dd/yyyy):
9. Approximate Age of Device: 1
10. Event Problem Codes (Refer to coding manual): Patient Code; Device Code
11. Report Sent to FDA? ☐ Yes (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☒ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: (Specify)
13. Report Sent to Manufacturer? ☐ Yes (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address:

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☒ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: 02
4. Device Manufacture Date (mm/yyyy): UNK
5. Labeled for Single Use? ☒ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method; Results; Conclusions
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Other: ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment
8. Usage of Device: ☒ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

NA

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices):
Mrs. Melanie Travis, Reg Compliance
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA
Site: Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

2. Phone Number: (901) 399-6233
3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 06/02/2008
5. (A)NDA # / IND # / STN# / PMA/ 510(k) # / Combination Product ☐ Yes / Pre-1938 ☐ Yes / OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☐ 15-day ☐ Follow-up #
8. Adverse Event Term(s):
9. Manufacturer Report Number: 1020279-2008-00179

MEDWATCH
3500A Facsimile (Back) ***(continued)***

Page 3 of 3

Smith & Nephew, Inc., Orthopaedic Division

Mfr Report #

UF/Importer Report # 1020279-2008-00179

FDA Use Only

ADDITIONAL INFORMATION

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71341113
Event Date 05/16/2008
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to a breakage of the device.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233

Device Event Key	1029765
MDR Report Key	1060210
Event Key	1018279
Report Number	1020279-2008-00178
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	06/16/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	06/16/2008
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71341113
Device LOT Number	06DM01764
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	05/27/2008
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	04/01/2006
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON POROUS STEM

back to search results

Catalog Number 71340111
Event Date 05/05/2008
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Manufacturer Narrative
Na.

Event Description
It was reported that revision surgery was performed due to a fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	POROUS STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Scott English 1450 Brooks Rd. Memphis , TN 38116

(901) 399 -5989

Device Event Key	1022034
MDR Report Key	1052807
Event Key	1010958
Report Number	1020279-2008-00163
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	05/27/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/27/2008
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340111
Device LOT Number	06GM01277
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	05/16/2008
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	07/01/2006
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Center for Devices and Radiological Health / CDRH

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON STEM back to search results

Catalog Number 71340117
Event Date 04/11/2008
Event Type Malfunction **Patient Outcome** Required Intervention;
Manufacturer Narrative
Na.

Event Description
It was reported that device was undersized, and did not function as intended, the surgeon performed add'l reaming of the pts bone to achieve a proper fit.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233

Device Event Key	1041160
MDR Report Key	1046223
Event Key	1004420
Report Number	1020279-2008-00149
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	05/09/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/12/2008
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Health Professional
Device Catalogue Number	71340117
Device LOT Number	05FM01493
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	04/17/2008
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	04/14/2008
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	06/01/2005
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Center for Devices and Radiological Health / CDRH

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON STEM back to search results

Catalog Number 71340117
Event Date 03/09/2005
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Manufacturer Narrative
Na.

Event Description
It was reported that revision surgery was perform due to dislocation.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233

Device Event Key	985589
MDR Report Key	1017335
Event Key	976101
Report Number	1020279-2008-00095
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	03/20/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/24/2008
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340117
Device LOT Number	81101075
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	03/06/2008
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
3500A Facsimile

Smith & Nephew, Inc., Orthopaedic Division

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Reisys International Inc., FDA Facsimile Approval: 4/17/2007

Mfr Report # 1020279-2008-00092
Dlr/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: W.Y. (In confidence)
2. Age at Time of Event: UNK or Date of Birth:
3. Sex: [ ] Female [X] Male
4. Weight: UNK lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death (mm/dd/yyyy)
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [X] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): UNK
4. Date of This Report (mm/dd/yyyy): 03/20/2008

5. Describe Event or Problem
It was reported that revision sugery was performed due to breakage of the stem.

6. Relevant Tests/Laboratory Data, Including Dates
UNK

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
UNK

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
1.
2.

2. Dose, Frequency & Route Used
1.
2.

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
1.
2.

4. Diagnosis for Use (Indication)
1.
2.

5. Event Abated After Use Stopped or Dose Reduced?
1. [ ] Yes [ ] No [ ] Doesn't Apply
2. [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
1.
2.

7. Exp. date
1.
2.

8. Event Reappeared After Reintroduction?
1. [ ] Yes [ ] No [ ] Doesn't Apply
2. [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Echelon
2. Common Device Name: Hip Stem
3. Manufacturer Name, City and State: Smith & Nephew Inc., Orthopaedic Div. 1450 Brooks Road Memphis, TN 38116 USA
4. Model #: NA
Lot #: UNK
Catalog #: UNK
Expiration Date (mm/dd/yyyy): UNK
Serial #: NA
Other #: NA
5. Operator of Device: [X] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy): UNK
7. If Explanted, Give Date (mm/dd/yyyy): UNK
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [X] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [X] No [ ] Returned to Manufacturer on (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
UNK

E. INITIAL REPORTER

1. Name and Address
Teresa Denson,
SMITH & NEPHEW ORTHO SPECIALTIES
1450 BROOKS ROAD
MEMPHIS, TN 38116, USA
Phone # 901-399-5354

2. Health Professional? [ ] Yes [X] No
3. Occupation: Legal
4. Initial Reporter Also Sent Report to FDA [ ] Yes [ ] No [X] Unk.

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH
3500A Facsimile (Back) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/ Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up #
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code; Device Code
11. Report Sent to FDA? ☐ Yes ☐ No *(mm/dd/yyyy)*
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ☐ No *(mm/dd/yyyy)*
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

Ms. Melanie Travis, Reg Compliance Specialist
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA
Site: Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

2. Phone Number: (901) 399-6233
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☒ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 03/06/2008
5. (A)NDA # / IND # / STN# / PMA/ 510(k) # / Combination Product ☐ Yes / Pre-1938 ☐ Yes / OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☐ 15-day ☐ Follow-up #
8. Adverse Event Term(s)
9. Manufacturer Report Number: 1020279-2008-00092

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☒ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☒ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*: UNK
5. Labeled for Single Use? ☒ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method; Results; Conclusions
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Other: ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment
8. Usage of Device: ☒ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

MEDWATCH
3500A Facsimile (Back) - *(continued)*

Smith & Nephew, Inc., Orthopaedic Division

MW Report #
1020279-2008-00092
UR/Importer Report #
FDA Use Only

ADDITIONAL INFORMATION

Adverse Event Report

SMITH & NEPHEW, INC. ECHELON STEM

back to search results

Catalog Number 71340514
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to a fracture of the device.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis, Reg Compliance 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233
Device Event Key	942788
MDR Report Key	973024
Event Key	933607

Report Number	1020279-2008-00001
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	01/02/2008
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/03/2008
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340514
Device LOT Number	01AM14333
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	12/04/2007
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	01/01/2001
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC.,/ ORTHOPAEDIC DIV. ECHELON STEM back to search results

Catalog Number 71340415
Event Date 08/17/2007
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Manufacturer Narrative
Na.

Event Description
It was reported that revision surgery was performed due to a fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC.,/ ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC.,/ ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Melanie Travis, 1450 Brooks Road Memphis , TN 38116 (901) 399 -6233
Device Event Key	887982

MDR Report Key	912475
Event Key	874708
Report Number	1020279-2007-00220
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	08/15/2007
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/14/2007
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340415
Device LOT Number	00805321
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	08/21/2007
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	08/15/2007
Was Device Evaluated By Manufacturer?	Yes
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
3500A Facsimile

Smith & Nephew, Inc., Orthopaedic Division

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Relays International Inc., FDA Facsimile Approval: 4/17/2007

MW Report # 1020279-2007-00186
OF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
UNK In confidence	80 or Date of Birth: UNK	☐ Female ☒ Male	UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☒ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☒ Hospitalization - initial or prolonged
- ☒ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
07/13/2007	07/16/2007

5. Describe Event or Problem

It was reported that revision surgery was performed due to a Prosthesis being fatigued, and broke.

6. Relevant Tests/Laboratory Data, Including Dates

It has been implanted approximately 4 1/2 yrs before breakage.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNK

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
1.
2.

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
# 1.	# 1.
# 2.	# 2.

4. Diagnosis for Use *(Indication)*
1.
2.

5. Event Abated After Use Stopped or Dose Reduced?
1. ☐ Yes ☐ No ☐ Doesn't Apply
2. ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. date
# 1.	# 1.
# 2.	# 2.

8. Event Reappeared After Reintroduction?
1. ☐ Yes ☐ No ☐ Doesn't Apply
2. ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
ECHELON

2. Common Device Name
Stem

3. Manufacturer Name, City and State
Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

4. Model #	Lot #	5. Operator of Device
NA	00504577A	☒ Health Professional
Catalog # 71340112	Expiration Date *(mm/dd/yyyy)* UNK	☐ Lay User/Patient
Serial # NA	Other # NA	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*
UNK	07/12/2007

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☒ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☒ Returned to Manufacturer on 07/18/2007 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*
UNK

E. INITIAL REPORTER

1. Name and Address
Scott Strzelecki,
WATERBURY HOSP HLTH CTR
64 ROBBINS ST
WATERBURY, CT 06708, USA

Phone # 203 573 6000

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	Sales	☐ Yes ☐ No ☒ Unk.

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH
3500A Facsimile (Back) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/ Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up #
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code; Device Code
11. Report Sent to FDA? ☐ Yes *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:
Mrs. Melanie Travis, Reg Compliance
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA
Site: Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

2. Phone Number: (901) 399-6233

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☒ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/16/2007

5. (A)NDA #: ; IND #: ; STN#: ; PMA/510(k) #: ; Combination Product ☐ Yes; Pre-1938 ☐ Yes; OTC Product ☐ Yes

6. If IND, Give Protocol #:

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☐ 15-day ☐ Follow-up #

8. Adverse Event Term(s):

9. Manufacturer Report Number: 1020279-2007-00186

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☒ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☒ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: 02
4. Device Manufacture Date *(mm/yyyy)*: UNK
5. Labeled for Single Use ? ☒ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method; Results; Conclusions
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Other: ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment
8. Usage of Device: ☒ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or 11. ☐ Corrected Data

NA

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH

3500A Facsimile (Back) ***(continued)***

MfR Report #
1020279-2007-00186
User/Importer Report #
FDA Use Only

ADDITIONAL INFORMATION